September 6, 2005

Dr. Susan Walker
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

New Dietary Ingredient Notification

Dear Dr. Walker:

Pursuant to 21 CFR § 190.6, pH Sciences is hereby notifying the Food and Drug Administration of our intent to market dietary supplements containing a new dietary ingredient.

1. **NAME AND ADDRESS OF MANUFACTURER OF DIETARY SUPPLEMENT THAT CONTAINS THE DIETARY INGREDIENT.**

pH SCIENCES, INC.
17230 12th Ave NE
Seattle, WA 98155
206-850-5987
206-364-5369 (FAX)

2. **NAME OF THE NEW DIETARY INGREDIENT THAT IS THE SUBJECT OF THE PRE-MARKET NOTIFICATION:**

Alka-Plex ®

The New Dietary Ingredient is Alka-Plex®, a proprietary combination of dietary minerals designed to help the user maintain a healthy pH level by providing a mild alkalizing effect. Alka-Plex® granules are made by using calcium carbonate powder as the carrier for magnesium hydroxide and potassium hydroxide. These minerals are then combined with microcrystalline cellulose, crosscarmelose sodium and magnesium stearate. This powder is then precisely agglomerated using a patented process[1] [2] whereby the resulting granules are in a form that provides protection for the integrity of the magnesium hydroxide and potassium hydroxide.

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Aims

3. DESCRIPTION OF THE DIETARY SUPPLEMENT THAT WILL CONTAIN THE NEW DIETARY INGREDIENT.

pH BALANCE™

The new dietary supplement that will contain the new dietary ingredient is labeled as pH Balance™. This product contains Alka-Plex® granules in a tableted form. The supplement will be packaged in opaque white plastic bottles containing 90 tablets each, or approximately on month's supply for supplementation.

3.1. LEVEL OF THE NEW DIETARY INGREDIENT IN THE DIETARY SUPPLEMENT.

The new dietary supplement contains Alka-Plex® granules at 1000mg prepared in tablet form, each tablet consisting of the following:

Calcium (as Calxium carbonate)-	220mg	or	22%DV
Magnesium (as Magnesium hydroxide)-	4mg	or	1%DV
Potassium (as Potassium hydroxide) -	35mg	or	1%DV

Tableting excipients are identified as microcrystalline cellulose and magnesium stearate.

3.2. CONDITIONS OF USE RECOMMENDED OR SUGGESTED IN LABELING OF THE DIETARY SUPPLEMENT.

It is well known that the average western diet is acidic in nature[3] [4] [5] especially when considering the amount of highly acidic beverages such as coffee and colas consumed on a daily basis. However, few individuals understand the nature of the body's pH level and the related influence on both health and wellness[6] and various health concerns. Using Alka-Plex® granules as the single ingredient, pH Balance™ is being introduced to provide the user with a mild alkalizing effect to neutralize the acids consumed on a daily basis.

A single serving size of pH Balance™ is one tablet. The suggested use is two to four tablets per day, not to exceed six tablets per day. pH Balance™ is not recommended for long term use. The label suggests that the user consult with a physician prior to using the supplement. The label suggests that the user consult a physician prior to use if the user is presently taking any medications or is under a physician's care. Precautions are listed on the supplement label are as follow: Contraindicated for women who are pregnant or nursing; Contraindicated for individuals with impaired kidney function, kidney disease.

Claims made on the label state that "pH Balance™ is designed to promote a healthy body pH and to reduce body acidity. This statement is accompanied by the FDA disclaimer as required by Law and stated as: "These statements have not been approved by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

4. HISTORY OF USE OR OTHER EVIDENCE OF SAFETY ESTABLISHING THAT THE DIETARY INGREDIENT, WHEN USED UNDER THE CONDITIONS RECOMMENDED, WILL REASONABLY BE EXPECTED TO BE SAFE.

4.1. Alka-Plex granules are made of 100% GRAS ingredients as listed below:

Calcium carbonate	-	21CFR 184.1191
Magnesium hydroxide	-	21CFR 184.1428
Potassium hydroxide	-	21CFR 184.1631

All excipients used in processing are GRAS or approved Food Additives, as listed below:

Magnesium stearate	-	21CFR 184.400
Microcrystaline cellulose	-	REGNUM - 977005-28-9
Crosscarmellose sodium		- 21CFR 175.105 (Listed as Carboxymethylcellulose)

As indicated by the report in the attached documents, the calcium, magnesium and potassium *do not* undergo any chemical change as a result of the proprietary agglomeration process.

4.2 History of Use

4.2.1 Alka-Plex® granules have been used in food/beverage products as an ingredient to reduce acidity since 1997. The product, Coffee Tamer™ was manufactured and marketed by Tamer International, holder of all intellectual property rights related to the formulation and manufacturing of Alka-Plex® granules. Tamer International licenses the ingredient, Alka-Pkex® and all related technology to pH Sciences, Inc.

4.2.2 In 1995, prior to marketing the ingredient, Tamer International requested GRAS approval on the Alka-Plex® granules for use in foods. Confirmation was given by CFSAN to Tamer International that the components of the product were acceptable for use in foods (See Attached Documents). Since, 1997, over 270,000 boxes of Coffee Tamer™ have been sold. There have been *no* adverse events reported. There has been *no* change to the ingredient since that time nor with the assignment or license of the formulation and related processes and technology by Tamer International to pH Sciences, Inc.

4.3 Safety/Toxicity/Cytotoxicity

4.3.1 *Acute Oral Toxicity of a Nutraceutical (Alka-Plex Granules) in Male and Female Sprague-Dawley Rats. SRI Study No. M384-05.* Experimental work performed between June 8, 2005 (Start date) and June 22, 2005 (Completion date) by Stanford Research Institute, BioSciences Division, Menlo Park, CA.. The objective of this study was to determine the maximum tolerated dose of a nutraceutical (Alka-Plex Ganules) in male and female Sprague-Dawley rats after a single oral dose administration. Clinical observations were recorded 2-5 hours post dose and once daily thereafter. Individual animal body weights were measured for each treatment group on Day 1 prior to dosing, Day 8 and Day 15 prior to necropsy of the animals. Gross necropsy was performed on all animals on Day 15.

All animals survived until the end of the study and had no adverse clinical signs or effects on body weight at any time during the study. Necropsy of all animals at the end of the study revealed gross pathologic findings in four females and in the 2g/Kg treatment group, which were considered unrelated to treatment with the test article. No grossly observable abnormalities occurred in any of the other animals in the study including those in the highest dose group (5g/Kg). In conclusion, the No Observable Adverse Effect Level (NOAEL) of Neutraceutical (Alka-Plex Granules) administered in a single oral dose was 5g/Kg, based on the parameters evaluated, and the maximum tolerated single oral dose is greater then 5g/Kg.

4.3.2 *MEM Endpoint Dilution Using L-929 Mouse Fibroblast Cells.* AIBMR Life Sciences, Inc. Puyallup, WA. The purpose of the study was to evaluate the ability of the test article to elicit a cytotoxic response in cultured mouse fibroblast cells employing L-929 cells. The results concluded that Alka-Plex Granules are considered non-toxic under the test conditions employed.

4.4 Human Clinical Data

4.4.1 *A Novel Therapy for Interstitial Cystitis: A Two Year Follow-Up Study. Nutrition Education and Consulting Service, East Syracuse, NY. May 2003. Susan E. Brown, Ph.D., CCN.* The objective of this study was to identify, locate and survey participants in a small outcome study measuring the effectiveness of Alka-Plex® granules provided to them in a variety of forms, in treating interstitial cystitis. During the initial three-month study, the average daily dosage of Alka-Plex® granules was significantly higher than the suggested use per the label on pH Balance™. Follow-up on the original participants began two years after the three-month review. Ten of the fifteen original participants interviewed continued to use Alka-plex® granules, most of whom used them to reduce acidity in coffee and foods. All were satisfied with results and none identified any adverse events associated with use.

We trust that the New Dietary Ingredient application and related documents contained herein provide your office with information as required by the FDA. If there are any questions regarding this submission, please contact me at (802) 223-2271 or by mail.

Respectfully submitted,

Dierdre Allen,
Consultant to pH Sciences

References

[1] United States Patent 6,270,708. Gurol August 7, 2001. Agglomerating and drying apparatus

[2] United States Patent 6,143,221 Gurol November 7, 2000 Agglomerating and drying apparatus

[3] Sebastian A, Frassetto LA, Sellmeyer DE, Merriam RL, Morris RC Jr. Estimation of the net acid load of the diet of ancestral preagricultural Homo sapiens and their hominid ancestors. **Am J Clin Nutr. 2002 Dec;76(6):1308-16.**

[4] Maurer M, Riesen W, Muser J, Hulter HN, Krapf R. Neutralization of Western diet inhibits bone resorption independently of K intake and reduces cortisol secretion in humans. **Am J Physiol Renal Physiol. 2003 Jan;284(1):F32-40. Epub 2002 Sep 24**

[5] Frassetto L, Morris RC Jr, Sellmeyer DE, Todd K, Sebastian A. Diet, evolution and aging--the pathophysiologic effects of the post-agricultural inversion of the potassium-to-sodium and base-to-chloride ratios in the human diet. **Eur J Nutr. 2001 Oct;40(5):200-13.**

[6] Frassetto L, Sebastian A Age and systemic acid-base equilibrium: analysis of published data. **J Gerontol A Biol Sci Med Sci. 1996 Jan;51(1):B91-9**